REMARKS/ARGUMENTS

In response to the Office Action mailed December 22, 2010, Applicants amend their application and request reconsideration in view of the amendments and the following remarks. In this amendment, claim 1 is amended, no claims have been cancelled without prejudice and no claims have been added, so that claims 1 and 6-8 are currently pending. No new matter has been entered.

Claims 1 and 6-8 were rejected under 35 USC 112, first paragraph and second paragraphs. Applicants have proposed to amend claim 1 to more clearly claim the invention. More specifically, applicants have used the data from Figure 64 which shows the concentration of rapamycin starting at about 1x10-10 or 0.1 nanomolar and rising. Accordingly, reconsideration and withdrawal of the rejection is respectfully submitted.

Claims 1 and 6-8 were rejected as being unpatentable over US Patent Publication No. 2002/0133183 to Lentz et al. (Lentz), U.S. Patent Application No. 2002/0004679 to Eury et al. (Eury), US 2003/0065382 to Fischell et al. (Fischell) and WO 96/34003 to Shull et al. (Shull). This rejection is respectfully traversed.

In order to make a finding of obviousness, an Examiner must (1) determine the scope and content of the prior art, including non-analogous art if it is in the field of endeavor reasonably related to the particular problem to which the claimed invention is directed, (2) ascertain the differences between the claimed invention and the prior art, considering both the prior art and claimed invention as a whole, and (3) resolve the level of ordinary skill in the art at the time of the invention, factoring in the creativity that one of ordinary skill in the art would employ as well as the Examiner's own knowledge and technical expertise.

It is respectfully submitted that the references taken as a whole fail to disclose or suggest all of the claimed limitations. Claim 1 claims a medical device comprising an

implantable structure, a basecoat matrix, including a combination of rapamycin and topotecan, in therapeutic dosages, incorporated in a first polymeric material, the basecoat matrix being affixed to the surface of the implantable medical device, the concentration of rapamycin being the ithe range framo about 0.1 nanomolar to about 1 nanaomolar abd the concentration of topotecan being about 300 nanomolar; and a topcoat, including a second polymeric material, affixed to the basecoat matrix for controlling the elution rate of the rapamycin and the topotecan, the first and second polymeric materials comprising chemically and physically incompatible chemistries for controlling the elution of the rapamaycin and the topotecan

Lentz discloses a medical device coated with various drugs and polymers. Fischell discloses a stent coated with a number of polymers, a number of drugs, including sirolimus. The drugs may be on the surface of the polymer or mixed in with the polymer. Eury discloses a stent coated with a topoisomerase inhibitor for treating restenosis. The stent may be fabricated from a polymer loaded with topotecan plus other drugs. Shull discloses the use of various analogs of camptothecin.

The references taken as a whole fail to disclose or even suggest a medical device with two specific drugs in the specific dosages in a two distinct polymer structure with chemically and physically incompatible chemistries. None of the references disclose or suggest the nanomolar concentrations of the two drugs used together in a matrix structure that is the product of phase separation as claimed. The extremely low concentration of rapamycin is possible because of the synergistic effect of the topotecan. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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